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August 4, 2021

Via ECF and E-Mail

Honorable Thomas J. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: In re Valsartan, Losartan and Irbesartan
Civil Action No. 19:md-2875-RBK-KMW

Dear Judge Vanaskie:

This firm represents Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. ("HLL") in the above referenced matter. We write in furtherance to the Court's directive during the July 28, 2021 Case Management Conference, to set forth a brief statement with respect to the documents for which Plaintiffs challenge HLL's privilege assertions.

Pursuant to Plaintiffs' Agenda Letter dated July 27, 2021, submitted to the Court in advance of the July 28, 2021 Case Management Conference (D.E. 1418), Plaintiffs challenge the following 20 documents which HLL has deemed privileged or partially privileged:

HLL353807 (Log Entry #1)

HLL00553806 (Log Entry #3)

HLL00553887 (Log Entry #6)

HLL00584156 (Log Entry #20)

HLL00595590 (Log Entry #31)

HLL00595638 (Log Entry #32)

HLL00619354 (Log Entry #40)

HLL00619378 (Log Entry #45)

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HLL00619391 (Log Entry #47)
HLL00619418 (Log Entry #56)
HLL00619423 (Log Entry #61)
HLL00773515 (Log Entry #113)
HLL01040879 (Log Entry #216)
HLL01040882 (Log Entry #219)
HLL01040883 (Log Entry #220)
HLL01040959 Log Entry #(231)
HLL01055029 (Log Entry #269)
HLL01057056 (Log Entry #300)
HLL01059805 (Log Entry #322) and
HLL01203202 (Log Entry #399).

The above referenced documents have been separately provided to Your Honor for in-camera inspection, by way of an *ex parte* secure file transfer link. HLL respectfully submits that the documents at issue are protected by the attorney-client privilege and work product doctrine.

A. Legal Predicate for the Court’s Analysis of HLL’s Claims of Protection by the Attorney Client Privilege and the Work Product Doctrine

Plaintiffs challenge 20 documents withheld by HLL in this litigation, which predominately involve communications, advice, questions, and drafts from outside consultants and outside Counsel. While it is well settled that merely copying an attorney on a document does not confer a privilege on the document, a document may be privileged even if an attorney is not included in the communication. Rather, “communications remain privileged if they assist the attorney to formulae and render legal

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advice.” In re Riddell Concussion Reduction Litigation, C.A. No. 13-7585 (JBS)(JS), 2016 WL 7108455, at *5 (D.N.J. Dec. 6, 2016). Indeed, the attorney-client privilege “protects only those disclosures necessary to obtain informed legal advice which might not have been made absent the privilege.” Fisher v. U.S., 425 U.S. 391, 403 (1976).

Many of the documents at issue presently involve mixed communications, including outside consultants and outside Counsel to HLL. Where there are mixed communications, the Court must determine “whether the primary purpose and content of the [communication] is predominately legal.” Rowe v. E.I., Dupont de Nemours & Co., C.A. Nos. 06-1810 and 06-3080 (RMB)(AMD), 2008 WL 4514092, at *11 (D.N.J. Sept. 30 2008). Moreover,

There is broad consensus in other jurisdictions that, if the non-legal aspects of the consultation are integral to the legal assistance given and the legal assistance is the primary purpose of the consultation, both the client’s communications and the lawyer’s advice and assistance that reveals the substance of those communications will be afforded the protection of the privilege.

Riddell, at *5.

To determine the primary purpose of a mixed communication, the Court must consider: (1) the context of the communication and the content of the document; (2) whether the legal purpose permeates the document and can be separated from the rest of the document, and (3) whether legal advice is specifically requested and the extent of the recipient list. Id. Thus, even in the absence of an attorney, these communications are privileged if they are necessary for the client to obtain legal advice. Westinghouse Elec. Corp. v. Republic of Philippines, 961 F.2d 1414, 1424 (3d Cir. 1991) (“Courts have held that the client may allow disclosure to an ‘agent’ assisting the attorney in giving legal advice to the client without waiving the privilege”); see also In re Grand Jury, 705 F.3d 133, 160 (3d Cir. 2012)

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(“‘Privileges persons’ include the client, the attorney(s), and any of their agents that help facilitate attorney-client communications or the legal representation.”)

HLL further asserts that several documents challenged by Plaintiffs are privileged pursuant to the work product doctrine. To qualify for the work product doctrine the document must “be reasonably clear based on the surrounding facts and the nature of the materials that they were in fact prepared or obtained because of pending or anticipated litigation.” Reich v. Hercules, Inc., 857 F. Supp. 367, 373 (D.N.J. 1994). Courts in this Circuit have found that the work product doctrine may apply where a document was prepared by a party’s agent. United Coal Cos. V. Powell Const. Co., 839 F.2d 958, 966-67 (3d Cir. 1988).

B. The Specific Documents Challenged by Plaintiffs Are Privileged or Partially Privileged

As an initial matter, Plaintiffs’ classifications of documents into 7 categories, as set forth in their August 3, 2021 letter, are inaccurate. (D.E. 1457). Plaintiffs’ first classification, “Communications with outside consultants are not privileged,” and fifth classification, “Communications that do not involve attorneys are not privileged,” are contradicted by the law of this Circuit, as set forth in Section A, *supra*. Plaintiffs’ second classification, “Routine business communications and communications involving mixed business information are not privileged,” is further misleading because several of the specific documents referenced by Plaintiffs in this section are dated after the initiation of this litigation, regarding the precise issues at the heart of this matter. Plaintiffs third classification, “Statements of fact are discoverable,” and fourth classification, “Merely copying Counsel on a communication does not make it privileged,” are correct, however the documents referenced by Plaintiffs specifically refer to communications that do far more than state facts or copy Counsel, but rather provide information that

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was utilized by Counsel in order to render legal advice and determine legal strategy regarding the products at issue in this case.

Turning to the documents at issue here, HLL sets forth an attorney client privilege with respect to HLL353807 (Log Entry #1), which is a document authored by outside Counsel in which Counsel discusses strategy decisions based upon information gleaned from the client during a confidential teleconference. Counsel outlines subsequent steps in anticipation of litigation, and provides advice as to how HLL can prepare for the events that Counsel anticipates will occur. Similarly, HLL553806 (Log Entry #3), follows up on that email and sets forth detailed issues that Counsel is advising HLL to prepare for in advance of a meeting with the FDA on March 13, 2019 regarding the products at issue in this case, *after* the initiation of the instant litigation. A subsequent draft of the same communication is set forth in HLL553887 (Log Entry #6) and HLL10203202 (Log Entry #399).

Further, HLL595590 (Log Entry #31) is a draft letter authored by HLL's outside Counsel dated April 23, 2020, in the midst of the instant litigation, to the FDA regarding the status of HLL's facilities with respect to the manufacture of the products at issue in this case. This document is not the final product, and falls into both attorney client privilege as well as attorney work product. This is made clear by HLL595638 (Log Entry #32), wherein outside Counsel is attaching the document and requesting edits. HLL1055029 (Log Entry #269) is similarly a non-final draft that is unequivocally marked as privileged and confidential attorney work product, setting forth edits by Counsel to a document that was prepared with the assistance of consultants and HLL employees. Another draft document authored by outside Counsel is set forth in HLL1057056 (Log Entry #300), which, too, is dated after the initiation of the instant litigation in September of 2019.

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A group of communications have been deemed privileged where consultants are transmitting edited versions of a document to be submitted to the FDA, and soliciting further edits and explanations. These documents are set forth in HLL619354 (Log Entry #40), HLL619378 (Log Entry #45), HLL619391 (Log Entry #47), HLL619418 (Log Entry #56), HLL619423 (Log Entry #61), and HLL2059805 (Log Entry #322). In these attendant communications, consultants are providing information directly to outside Counsel in order for Counsel to render its legal advice and finalize its submission to the FDA regarding the manufacturing facilities of the products at issue in this litigation.

HLL584156 (Log Entry #20) is a document that requests information specifically requested by HLL's Counsel "in the valsartan litigation." This document unequivocally was prepared for the instant litigation, at the undersigned Counsel's request and falls squarely within the confines of attorney client privilege.

The documents HLL773515 (Log Entry #113), HLL1030879 (Log Entry #216), HLL1040882 (Log Entry #219), HLL1040883 (Log Entry #220), HLL1030969 (Log Entry #231) are a group of communications with outside Counsel and outside consultants, dated March of 2019, after the initiation of this litigation, regarding the specific products at issue in this litigation and documents to be submitted to the FDA. The consultants provide information to outside Counsel to facilitate finalization of the submission to the FDA, which is directly pertinent to the instant litigation.

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Accordingly, HLL respectfully submits that the documents challenged by Plaintiffs are, indeed, privileged and request that the Court So Order this finding. We thank the Court for its time and consideration in this matter.

Respectfully submitted,

s/ Eric I. Abraham
ERIC I. ABRAHAM

Encl.